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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 426,548	10 22 1999	DAVID ROBBINS	DEX-0054	2041

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EXAMINER

WOITACH, JOSEPH T

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 01/14/2003

28

Please find below and/or attached an Office communication concerning this application or proceeding.

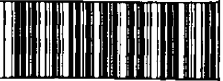
# Office Action Summary

Application No.  
**09/426,548**

Applicant(s)  
**Robbins et al.**

Examiner  
**Joseph Weitach**

Art Unit  
**1632**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Nov 1, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 2, 3, and 9 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 2, 3, and 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO 892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s).
- 4) ☐ Interview Summary (PTO-413) Paper No(s).
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on November 1, 2002, paper number 25, has been entered.

**DETAILED ACTION**

This application claims benefit to provisional application 60/105,180, filed October 22, 1998.

Applicants amendment filed November 1, 2002, paper number 27 has been received and entered. Claim 9 has been amended. Claims 2, 3 and 9 are pending and currently under examination.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 2, 3 and 9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 9 is vague and indefinite in the recitation of an 'oligonucleotide probe hybridizing' because the specific conditions for hybridization are not clearly set forth in the claim or defined in the specification. The metes and bounds of the claim are indefinite because an oligonucleotide under various hybridization conditions may or may not meet the limitations of the claims. For example, a 7 base pair oligonucleotide which specifically binds to a particular sequence at low stringency conditions would not bind at high stringency conditions. Because no specific hybridization conditions are set forth, the metes and bounds of the claims can not be determined because the extent of homology can not be defined. Claims 2 and 3 are included in the basis of the rejection because they depend on the use of the oligonucleotides of claim 9 and do not further clarify the basis of the rejection.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(c) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who

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has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 2, 3 and 9 stand rejected under 35 U.S.C. 102(b) as being anticipated by Weber *et al.*

Claim 9 has been amended to delete [hMLH mutant 2] which was anticipated by cited reference. With respect to the remaining mutations, Applicants argue that Weber *et al.* do not specifically teach hMLH1 mutant 1, hMSH2 mutant 1, hMSH2 mutant 2 and hMSH2 mutant 3 and thus claims 2 and 3 cannot be anticipated since these mutations are not taught. Applicants arguments have been fully considered but not found persuasive.

As discussed above in the 112, second paragraph rejection the metes and bounds of the specific oligonucleotide encompassed by claim 9 and used in the methods of claims 2 and 3 can vary depending on the specific hybridization conditions one may use. Further, claims 2 and 3 encompass the method of screening the DNA sample, however since a the screening does not involve specifically screening for a specific mutation, the presence or the absence of a mutation is indicative of the screening method. Weber *et al.* teach a method and the appropriate primers to do genomic sequencing of MLH1 and MSH2, and detect mutations predictive of heredity nonpolyposis colorectal cancer (whole document, particularly Table 1 and 2). Therefore, the claim is anticipated by Weber *et al.*

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Claims 2, 3 and 9 stand rejected under 35 U.S.C. 102(e) as being anticipated by Liskay *et al.*

Claim 9 has been amended to delete [hMLH mutant 2] which was anticipated by cited reference. With respect to the remaining mutations, Applicants argue that Liskay *et al.* do not specifically teach hMLH1 mutant 1, hMSH2 mutant 1, hMSH2 mutant 2 and hMSH2 mutant 3 and thus claims 2 and 3 cannot be anticipated since these mutations are not taught. Applicants arguments have been fully considered but not found persuasive.

As discussed above, claims 2 and 3 encompass the method of screening the DNA sample, however since a the screening does not involve specifically screening for a specific mutation, the presence or the absence of a mutation is indicative of the screening method. Liskay *et al.* teach a method and the appropriate primers for the detection of mutations in MLH1 and MSH2 which are associated and predictive of heredity nonpolyposis colorectal cancer (whole document and in particular figure 1, and sequences of figures 2-5, 13-16). Therefore, the claim is anticipated by Liskay *et al.*

### ***Conclusion***

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Woitach

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